

(19) World Intellectual Property
Organization
International Bureau



(43) International Publication Date
29 December 2004 (29.12.2004)

PCT

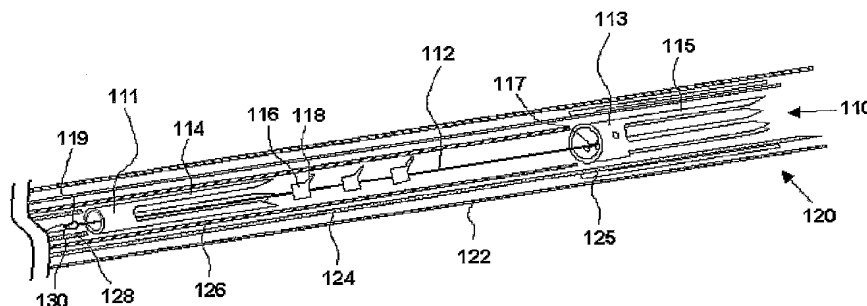
(10) International Publication Number
WO 2004/112658 A1

- (51) International Patent Classification⁷: **A61F 2/24**
- (21) International Application Number:
PCT/US2004/019745
- (22) International Filing Date: 21 June 2004 (21.06.2004)
- (25) Filing Language: English
- (26) Publication Language: English
- (30) Priority Data:
60/480,195 20 June 2003 (20.06.2003) US
60/480,472 20 June 2003 (20.06.2003) US
60/503,035 15 September 2003 (15.09.2003) US
- (71) Applicant: **MEDTRONIC VASCULAR INC.** [US/US];
IP Legal Dept., 3576 Unocal Place, Santa Rosa, California
95403 (US).
- (72) Inventors: **BLOOM, Eliot**; 601 Putney Hill Road, Hop-
kinton, New Hampshire 03229 (US). **DOUK, Nareak**;
905 Lakeview Avenue, Lowell, Massachusetts 01850
(US). **HORRIGAN, John**; 33 Berrywood Lane, Bever-
ly, Massachusetts 01915 (US). **HUYNH, Rany**; 125
Chiswick Road, #204, Brighton, Massachusetts 02135
(US). **RAFIEE, Nasser**; 39 Abbot Street, Andover, Mass-
achusetts 01810 (US).
- (74) Agent: **MARESH, Catherine**; IP Legal Dept., 3576 Un-
ocal Place, Santa Rosa, California 95403 (US).
- (81) Designated States (*unless otherwise indicated, for every
kind of national protection available*): AE, AG, AL, AM,
AT, AU, AZ, BA, BB, BG, BR, BW, BY, BZ, CA, CH, CN,
CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, EG, ES, FI,
GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE,
KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD,
MG, MK, MN, MW, MX, MZ, NA, NI, NO, NZ, OM, PG,
PH, PL, PT, RO, RU, SC, SD, SE, SG, SK, SL, SY, TJ, TM,
TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, YU, ZA, ZM,
ZW.
- (84) Designated States (*unless otherwise indicated, for every
kind of regional protection available*): ARIPO (BW, GH,
GM, KE, LS, MW, MZ, NA, SD, SL, SZ, TZ, UG, ZM,
ZW), Eurasian (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM),
European (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI,
FR, GB, GR, HU, IE, IT, LU, MC, NL, PL, PT, RO, SE, SI,
SK, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ,
GW, ML, MR, NE, SN, TD, TG).
- Published:
— with international search report

[Continued on next page]

(54) Title: TENSIONING DEVICE AND SYSTEM FOR TREATING MITRAL VALVE REGURGITATION

100



(57) Abstract: A system for treating mitral valve regurgitation comprises tensioning device 110 slidably received within delivery catheter 120. The tensioning device includes tether 112 linking proximal anchoring member 111 and distal anchoring member 113. At least one of the anchoring members 111 includes an elastic portion that flexes in response to a heartpulsebeat when tensioning device 110 is positioned across a chamber of a heart. Tether 112 includes at least one locking member 116, 118 initially positioned between the anchoring members 111.

WO 2004/112658 A1



— *before the expiration of the time limit for amending the claims and to be republished in the event of receipt of amendments*

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

- 1 -

TENSIONING DEVICE AND SYSTEM FOR TREATING MITRAL VALVE REGURGITATION

PRIORITY CLAIM

This application claims the benefit of U.S. Provisional Application No. 60/480,195 filed June 20, 2003; U.S. Provisional Application No. 60/480,472 filed June 20, 2003; and U.S. Provisional Application No. 60/503,035 filed September 15, 2003; the entirety of each of which is hereby incorporated by reference.

TECHNICAL FIELD

[001] This invention relates generally to medical devices and particularly to a system and method for treating mitral valve regurgitation.

BACKGROUND OF THE INVENTION

[002] The heart is a four-chambered pump that moves blood efficiently through the vascular system. Blood enters the heart through the vena cava and flows into the right atrium. From the right atrium, blood flows through the tricuspid valve and into the right ventricle, which then contracts and forces blood through the pulmonic valve and into the lungs. Oxygenated blood returns from the lungs and enters the heart through the left atrium and passes through the bicuspid mitral valve into the left ventricle. The left ventricle contracts and pumps blood through the aortic valve into the aorta and to the vascular system.

[003] The mitral valve consists of two leaflets (anterior and posterior) attached to a fibrous ring or annulus. In a healthy heart, the mitral valve leaflets overlap during contraction of the left ventricle and prevent blood from flowing back into the left atrium. However, due to various cardiac diseases, the mitral valve annulus may become distended, causing the leaflets to remain partially open during ventricular contraction and thus allowing regurgitation of blood into the left atrium. This results in reduced ejection volume from the left ventricle, causing the left ventricle to compensate with a larger stroke volume. The increased workload eventually results in dilation

- 2 -

and hypertrophy of the left ventricle, further enlarging and distorting the shape of the mitral valve. If left untreated, the condition may result in cardiac insufficiency, ventricular failure, and death.

[004] It is common medical practice to treat mitral valve regurgitation by valve replacement or repair. Valve replacement involves an open-heart surgical procedure in which the patient's mitral valve is removed and replaced with an artificial valve. This is a complex, invasive surgical procedure with the potential for many complications and a long recovery period.

[005] Mitral valve repair includes a variety of procedures to repair or reshape the leaflets to improve closure of the valve during ventricular contraction. If the mitral valve annulus has become distended, a common repair procedure involves implanting an annuloplasty ring on the mitral valve annulus. The annuloplasty ring generally has a smaller diameter than the annulus, and when sutured to the annulus, the annuloplasty ring draws the annulus into a smaller configuration, bringing the mitral valve leaflets closer together and providing improved closure during ventricular contraction.

[006] Annuloplasty rings may be rigid, flexible, or have both rigid and flexible segments. Rigid annuloplasty rings have the disadvantage of causing the mitral valve annulus to be rigid and unable to flex in response to the contractions of the ventricle, thus inhibiting the normal movement of the mitral valve that is required for it to function optimally. Flexible annuloplasty rings are frequently made of Dacron® fabric and must be sewn to the annular ring with a line of sutures. This eventually leads to scar tissue formation and loss of flexibility and function of the mitral valve. Similarly, combination rings must generally be sutured in place and also cause scar tissue formation and loss of mitral valve flexibility and function.

[007] Annuloplasty rings have been developed that do not require suturing. U.S. Patent No. 6,565,603 discloses a combination rigid and flexible annuloplasty ring that is inserted into the fat pad of the atrioventricular groove, which surrounds the mitral valve annulus. Although this device avoids the need for sutures, it must be placed within the atrioventricular groove with great care to prevent tissue damage to the heart.

- 3 -

[0008] U.S. Patent No. 6,569,198 discloses a flexible annuloplasty ring designed to be inserted into the coronary sinus, which is located adjacent to and partially surrounds the mitral annulus. The prosthesis is shortened lengthwise within the coronary sinus to reduce the size of the mitral annulus. However, the coronary sinus in a particular individual may not wrap around the heart far enough to allow effective encircling of the mitral valve, making this treatment ineffective.

[0009] U.S. Patent No. 6,210,432 discloses a flexible elongated device that is inserted into the coronary sinus and adapts to the shape of the coronary sinus. The device then undergoes a change that causes it to assume a reduced radius of curvature and, as a result, causes the radius of curvature of the coronary sinus and the circumference of the mitral annulus to be reduced. While likely to be effective for modest changes in the size or shape of the mitral annulus, this device may cause significant tissue compression in patients requiring a larger change in the configuration of the mitral annulus.

[0010] U.S. Patent Application Publication 2003/0105520 discloses a flexible elongated device that is inserted into the coronary sinus and anchored at each end by a self-expanding, toggle bolt-like anchor that expands and engages the inner wall of the coronary sinus. Application WO02/076284 discloses a similar flexible elongated device that is inserted into the coronary sinus. This device is anchored at the distal end by puncturing the wall of the coronary sinus, crossing the intervening cardiac tissue, and deploying the anchor against the exterior of the heart in the pericardial space. The proximal end of the elongated member is anchored against the coronary ostium, which connects the right atrium and the coronary sinus. Once anchored at each end, the length of either of the elongated devices may be adjusted to reduce the curvature of the coronary sinus and thereby change the configuration of the mitral annulus. Due to the nature of the anchors, both of these devices may cause significant damage to the coronary sinus and surrounding cardiac tissue. Also, leaving a device in the coronary sinus may result in formation and breaking off of a thrombus that may pass into the right atrium, right ventricle, and ultimately the lungs, causing a pulmonary embolism. Another

- 3 -

- 4 -

disadvantage is that the coronary sinus is typically used for placement of a pacing lead, which may be precluded with the placement of the prosthesis in the coronary sinus.

[0011] U.S. Patent No. 6,616,684 discloses a splint assembly that is positioned transverse the left ventricle to treat mitral valve leakage. In one embodiment, the assembly is delivered through the right ventricle. One end of the assembly is anchored outside the heart, resting against the outside wall of the left ventricle, while the other end is anchored within the right ventricle, against the septal wall. The heart-engaging portions of the assembly, i.e., the anchors, are essentially flat and lie snugly against their respective walls. The length of the splint assembly is either preset or is adjusted to draw the two walls of the chamber toward each other.

[0012] The splint assembly may be delivered endovascularly, which offers distinct advantages over open surgery methods. However, the endovascular delivery technique is complicated, involving multiple delivery steps and devices, and requiring that special care be taken to avoid damage to the pericardium and lungs. First, a needle or guidewire is delivered into the right ventricle, advanced through the septal wall, and anchored to the outer or free wall of the left ventricle using barbs or threads that are rotated into the tissue of the free wall. Visualization is required to ensure the needle does not cause damage beyond the free wall. A delivery catheter is then advanced over the needle, piercing both the septal wall and the free wall of the ventricle. The catheter is anchored to the free wall with balloons inflated on either side of the wall. A tension member is then pushed through the delivery catheter such that a distal anchor is positioned outside the heart. During the catheter anchoring and distal anchor positioning steps, care must be taken to guard against damaging the pericardium or lungs, and insufflation of the space between the myocardium and the pericardial sac may be desirable. A securing band is advanced over the tension member to expand the distal anchor and/or maintain it in an expanded configuration. The catheter is withdrawn, and a second (proximal) anchor is advanced over the tension member using a deployment tool and positioned within the right ventricle against the septal wall. A tightening device then holds the second anchor in a

- 4 -

- 5 -

position so as to alter the shape of the left ventricle. Excess length of the tension member is thermally severed prior to removal, again posing some risk to tissue in and around the heart.

[0013] Therefore, it would be desirable to provide a system and method for treating mitral valve regurgitation that overcome the aforementioned and other disadvantages.

SUMMARY OF THE INVENTION

[0014] One aspect of the present invention is a tensioning device for treating mitral valve regurgitation, comprising a tether and proximal and distal anchoring members. The distal anchoring member is positioned adjacent to a distal end of the tether, and the proximal anchoring member is positioned adjacent to a proximal end of the tether. At least one of the anchoring members includes an elastic portion that flexes in response to a heartbeat when the tensioning device is positioned across a chamber of a heart.

[0015] Another aspect of the present invention is a system for treating mitral valve regurgitation that includes the above-described tensioning device and further comprises a delivery catheter. The tensioning device is slidably received within a lumen of the delivery catheter.

[0016] The present invention includes another system for treating mitral valve regurgitation that comprises a delivery catheter and a tensioning device slidably received within a lumen of the delivery catheter. The tensioning device includes a tether and proximal and distal anchoring members, the distal anchoring member positioned adjacent to a distal end of the tether, and the proximal anchoring member positioned adjacent to a proximal end of the tether. At least one locking member is affixed to the tether. When the locking member is pulled from an initial position between the anchoring members to a locked position proximal the proximal anchoring member, the length of the tether is adjusted to change the proximity of the anchoring members one to the other.

[0017] Another aspect of the present invention is a method of treating mitral valve regurgitation by affecting a mitral valve annulus. A first wall of a

- 6 -

chamber of a heart is pierced. A distal anchoring member is engaged with a second wall of the heart chamber. A proximal anchoring member is engaged with the first wall of the heart chamber. A locking member affixed to a tether linking the proximal and distal anchors is pulled from an initial position between the two anchors to a locked position proximal the proximal anchor.

[0018] The aforementioned and other features and advantages of the invention will become further apparent from the following detailed description of the presently preferred embodiments, read in conjunction with the accompanying drawings, which are not to scale. The detailed description and drawings are merely illustrative of the invention rather than limiting, the scope of the invention being defined by the appended claims and equivalents thereof.

BRIEF DESCRIPTION OF THE DRAWINGS

[0019] **FIG. 1** is an isometric view of one embodiment of a tensioning device in accordance with the present invention, shown in the context of a system for treating mitral valve regurgitation in accordance with the present invention, the tensioning device being shown in toto, and a guiding catheter being shown in cross section ;

[0020] **FIGS. 2** and **3** are isometric cutaway views of the device and system of **FIG. 1** at two stages of deployment of the tensioning device;

[0021] **FIGS. 4A** and **4B** are isometric views of an alternative anchoring member in accordance with the present invention, showing the anchoring member in a compressed and an expanded configuration, respectively;

[0022] **FIGS. 5A** and **5B** are side views of a tether portion and alternative locking members in accordance with the present invention, showing the locking members in unlocked and locked configurations, respectively; and

[0023] **FIG. 6** is a schematic view illustrating the placement of the tensioning device across a left ventricle, in accordance with the present invention; and

- 6 -

- 7 -

[0024] The same reference numbers are used throughout the drawings to refer to the same parts.

DETAILED DESCRIPTION OF THE PRESENTLY PREFERRED EMBODIMENTS

[0025] One aspect of the present invention is a tensioning device for treating mitral valve regurgitation. One embodiment of the device, in accordance with the present invention, is illustrated in **FIGS. 1–3** at **110**.

[0026] Tensioning device **110** is designed to be positioned across a chamber of a heart using minimally invasive catheterization techniques. Although described below in the context of treating mitral valve regurgitation by reducing or limiting lateral distension of the left ventricle as the heart beats, device **110** may be deployed at other locations in the heart and is readily adapted to a wide variety of uses, including treating ischemic or dilated cardiomyopathy.

[0027] Tensioning device **110** includes proximal anchoring member **111** positioned adjacent to the proximal end of tether **112**, and distal anchoring member **113** positioned adjacent to the distal end of tether **112**. As used herein, the terms “distal” and “proximal” are with reference to the treating clinician during deployment of the device.

[0028] At least one of the anchoring members includes an elastic portion that flexes in response to a heartbeat when tensioning device **110** is positioned across the heart chamber. In the present embodiment, the elastic portion comprises a plurality of flexible arm segments. As tension is exerted on the device due to the motion of the beating heart, the arms flex, thereby providing a shock absorbing effect. This effect not only reduces the risk of tensioning device **110** failing due to structural fatigue, but also reduces localized compressive pressure on tissue against which the flexing anchoring member rests.

[0029] In the present embodiment, each of proximal and distal anchoring members **111** and **113** comprises a section of nitinol tubing having evenly spaced longitudinal slots cut into a distal portion of the tubing to form flexible

- 7 -

- 8 -

arm segments **114** and **115**, respectively. The slots may be, for example, rectangular, u-shaped, v-shaped, or Ω -shaped (omega-shaped). In another embodiment, the arm segments may be formed separately from the body of the anchoring member and assembled to create an integral whole. In either embodiment, the arm segments of the anchoring members comprise a biocompatible material capable of being preset into an anchor shape. Such materials include, but are not limited to, a nickel-titanium alloy, a nickel-cobalt alloy, another cobalt alloy, a thermoset plastic, stainless steel, a suitable biocompatible shape-memory material, a suitable biocompatible superelastic material, combinations thereof, and the like.

[0030] During manufacture, the arm segments are bent outward and heat set or otherwise set such that each of the arm segments is self-deploying radially outward at an angle of between 40 and 90 degrees from the longitudinal axis of the anchoring member when the anchoring member is released from delivery catheter **120**. **FIG. 1** shows the flexible arm segments in a radially compressed, folded configuration while the anchoring members are within delivery catheter **120**. **FIGS. 2** and **3** show the anchoring members self-expanded after having been released from delivery catheter **120**, which is described below. For better viewing of device **110**, the walls of the heart chamber across which tensioning member **110** is to be positioned are not shown in **FIGS. 1–3**.

[0031] In the present embodiment, proximal anchoring member **111** is intended to be deployed such that it is positioned with arm segments **114** resting against the right ventricular surface of the septal wall. In an alternative embodiment, proximal anchoring member **111** may be deployed such that arm segments **114** are embedded within the septal wall. For this embodiment, the arm segments would be directed proximally when in a radially compressed, folded configuration, rather than distally as shown in **FIG. 1**.

[0032] As illustrated in **FIGS. 1–3**, proximal anchoring member **111** includes three flexible arm segments **114** cut into a distal portion of the anchoring member. The number of arm segments may be varied, with the

- 8 -

- 9 -

number, size, and shape of the arm segments selected to cover an area larger in diameter than the diameter of a hole that is pierced through the septal wall to deliver tether **112** and distal anchoring member **113** into the left ventricle. Proximal anchoring member **111** may also apply a contractive force around the hole, helping to prevent leakage of blood through the hole and eliminating the need for a sealing member. Tensioning device **110** may, however, include one or more sealing members adjacent to one or both of the anchoring members if desired. An example of a sealing member is shown in phantom at **425** in **FIGS. 4A** and **4B**. Where an anchoring member is deployed within a wall, the anchoring member would not necessarily benefit from having a sealing member.

[0033] In the present embodiment, distal anchoring member **113** is intended to be released such that arm segments **115** expand radially within the tissue of (i.e., between the surfaces of) the outside or free wall of the left ventricle. Embedding the arm segments within the wall rather than positioning them against the outside surface of the wall reduces the risk of damage to structures beyond the wall such as the pericardial sac and the lungs. However, distal anchoring member **113** may be deployed outside the free wall if desired, with arm segments **115** resting against the outer surface of the wall. The arm segments would be directed proximally when in a radially compressed, folded configuration within the delivery catheter, rather than distally as shown in **FIG. 1**.

[0034] As illustrated in **FIGS. 1–3**, distal anchoring member **113** includes four flexible arm segments **115** cut into a distal portion of the anchoring member. The four-pronged shape of distal anchoring member **113** provides good retention within the free wall of the left ventricle; however, the number of arm segments may be varied.

[0035] In the present embodiment, only proximal anchoring member **111** flexes in response to a heart beat. Distal anchoring member **113** is not intended to flex within the tissue of the wall in which it is embedded. In another embodiment, in which distal anchoring member **113** is positioned

- 10 -

outside the heart wall, both the proximal and distal anchoring members would flex in response to the motion of a beating heart.

[0036] One of ordinary skill in the art will recognize that the shapes of the anchoring members may be varied from those shown in **FIGS. 1–3**. For example, an alternative anchoring member **410** capable of flexing in response to a heart beat is shown in a radially compressed configuration in **FIG. 4A** and in a self-expanded configuration in **FIG. 4B**. In this design, the curve of each arm segment **415** is focused at the base of the segment, spreading the deflection load over roughly three-fourths of a circle.

[0037] When positioned across a heart chamber, the anchoring members and tether are under continuously varying tension due to the motion of the beating heart. To withstand this environment, tether **112** comprises a biocompatible metallic or polymeric material that combines flexibility, high strength, and high fatigue resistance. For example, tether **112** may be formed using materials such as stainless steel, titanium, a nickel-titanium alloy, a nickel-cobalt alloy, another cobalt alloy, tantalum, polypropylene, polyethylene, polyurethane, polytetrafluoroethylene (PTFE), polyester (Dacron®), nylon, combinations thereof, and the like. In one embodiment, tether **112** may comprise a polymeric filament having an elastic property that decreases linearly or in an abrupt step when a desired tether length is reached. Tether **112** may also comprise a pseudo-elastic nickel-titanium wire that has a helical shape (such as is seen in a portion of tether **512** of **FIGS. 5A** and **5B**) and permits changes in length in response to varying tension loads. When the helix is straightened, the elastic property of the tether decreases, preventing lateral distension of the heart chamber beyond a set limit.

[0038] An antithrombotic component may be included in the chemical composition of a polymeric filament. Alternatively, a polymeric or metallic tether may be coated with a polymer that releases an anticoagulant and thereby reduces the risk of thrombus formation. If desired, additional therapeutic agents or combinations of agents may be used, including antibiotics and anti-inflammatories.

- 10 -

- 11 -

[0039] Distal anchoring member **113** is fixedly attached to tether **112** using a pin **117** that extends through the anchoring member and to which the tether is attached. Other methods of attaching distal anchoring member **113** to tether **112** include having an enlarged distal portion of tether **112** positioned distal to the distal anchoring member. Thus, tether **112** passes through a central lumen of distal anchoring member **113**, and the enlarged distal portion of tether **112** prevents the tether from separating from the distal anchoring member. The distal enlargement may be a knot, a bead, or an enlargement mounted onto or formed into the tether.

[0040] Proximal anchoring member **111** is variably attached to tether **112** by a locking member affixed to tether **112**. At least one locking member is drawn from an initial position between the two anchoring members to a position proximal the proximal anchoring member. This not only locks the proximal anchoring member onto the tether, but also adjusts the length of the tether to change the proximity of the anchoring members one to the other.

[0041] In the present embodiment, multiple locking members **116** are spaced apart on tether **112** between proximal anchoring member **111** and distal anchoring member **113**, affixed by, for example, crimping or swaging the locking members onto the tether, confining each locking member with a knot or other enlargement on either side of the locking member, or using an adhesive. The length of the tether between the two anchoring members is adjusted and maintained at the chosen length by drawing an appropriate number of locking members through a central lumen of proximal anchoring member **111**.

[0042] As shown in **FIGS. 1–3**, the locking members are formed of short sections of tubing having an outer diameter selected to provide a close sliding fit with the inner diameter of proximal anchoring member **111**. Each locking member includes a flexible tab **118** flaring out at an angle from the longitudinal axis of the locking member. The tab extends from the distal end of the locking member and flares out at approximately a 45-degree angle. The locking member comprises a shape-memory material, and the tab is heat set or otherwise set into its flared position.

- 11 -

- 12 -

[0043] As a locking member is drawn through the lumen of proximal anchoring member **116**, its tab is bent back into alignment with the body of the locking member in order to fit through the lumen. Once proximal to the anchoring member and no longer constrained by the lumen of proximal anchoring member **116**, the tab resumes its preset shape. The flaring tab prevents the locking member from passing back through the proximal anchoring member, thereby locking proximal anchoring member **116** onto tether **112**.

[0044] Any mechanism allowing tether motion in a proximal direction and preventing tether motion in a distal direction is suitable for the locking member. For example, locking members may be as shown in **FIGS. 5A** and **5B** at **513**, **514**, and **515**. Each locking member is formed of a short section of tubing that is cut at a 90-degree angle at the proximal end and at an angle of approximately 45 degrees at the distal end. The outer diameter of the locking member is selected to fit slidingly through the lumen of the proximal anchoring member. In order to set the tether length, the tether and at least one locking member are drawn proximally through the lumen of the proximal anchoring member. When the desired length of tether remains between the proximal and distal anchoring members, tether **512** is allowed to move in a distal direction until the locking member proximally adjacent to the proximal anchoring member engages the anchoring member, causing the locking member to cock at an angle, as shown by locking member **514** in **FIG. 4B**. At this angle, the elliptical distal face of locking member **514** abuts the proximal end of the proximal anchoring member, and the major axis of the locking member elliptical distal end is greater than the inside diameter of the proximal anchoring member. Consequently, the locking member cannot be drawn distally through the anchoring member at the angle shown in **FIG. 5B**. However, if the treating clinician wishes to readjust the locked tensioning device to increase the length of the tether between the proximal and distal anchoring members, tether **512** can be again pulled in a proximal direction, thereby straightening locking member **514** to the configuration shown in **FIG. 5A** and freeing it from engagement with the proximal anchoring member. Locking member **514** can then pass distally back through the proximal

- 12 -

- 13 -

anchoring member. Thus, the length of the tether may be readjusted and relocked.

[0045] Tether **112** includes a loop **119** on the proximal end of the tether. A length of suture material or another strong, thin, filament **130** passes through loop **119**. The filament is roughly doubled over onto itself with the ends of the filament adjacent to each other and two portions of the filament extending away from loop **119**. The filament is sized such that the ends of the filament extend outside the patient when tensioning device **110** is positioned at the treatment site. A treating clinician pulls both ends of the filament simultaneously to draw the appropriate number of locking members through proximal anchoring member **111**. Once the length of the tether has been adjusted and proximal anchoring member **111** has been locked onto tether **112**, filament **130** is removed by releasing one end of the filament and pulling on the other end until the filament is withdrawn from the patient. This design eliminates the need to thermally cut or otherwise sever tether **112** after tensioning device **110** has been deployed at the treatment site.

[0046] Other arrangements may be used to releasably engage a draw filament with the tether of a tensioning device such as is described herein. Examples include a ball and a socket, a hook and a ring, and a collet and a pin.

[0047] To ensure proper positioning, it is desirable that tensioning device **110** be visible using fluoroscopy, echocardiography, intravascular ultrasound, angiography, or another means of visualization. Where fluoroscopy is utilized, any or all of tensioning device **110** may be coated with a radiopaque material, or a radiopaque marker may be included on any portion of the device that would be useful to visualize.

[0048] Another aspect of the present invention is a system for treating mitral valve regurgitation that includes tensioning device **110** described above. The system, shown generally by numeral **100** in **FIGS. 1-3**, further includes delivery catheter **120**.

- 13 -

- 14 -

[0049] Tensioning device **110** is slidably received within a lumen of delivery catheter **120** for delivery to and deployment at the treatment area. As best seen in **FIG. 1**, delivery catheter **120** comprises guiding sheath **122**, piercing tube **124**, holding tube **126**, and push cylinder **128**. Piercing tube **124** is slidable within a lumen of guiding sheath **122**, holding tube **126** is slidable within a lumen of piercing tube **124**, and push cylinder **128** is slidable within a lumen of holding tube **126**. Thus, delivery catheter **120** comprises four separate, concentric members, each slidable to be individually extended or retracted as needed to deliver tensioning device **110**.

[0050] Guiding sheath **122** comprises a flexible, biocompatible material such as polyurethane, polyethylene, nylon, or polytetrafluoroethylene (PTFE). Guiding sheath **122** has a preformed or steerable distal tip that is capable of assuming a desired bend with respect to the longitudinal axis of the sheath, for example, a ninety-degree bend.

[0051] Piercing tube **124** comprises the same or a different biocompatible material from that used to form guiding sheath **122**. In the present embodiment, the distal end of piercing tube **124** is angle-cut to form a sharp edge able to pierce into or through myocardial tissue. Thus, where tensioning member **110** is to be delivered transluminally, piercing tube **124** must be flexible enough to be delivered through vasculature to the treatment area while still rigid enough to pierce myocardial tissue.

[0052] Piercing tube **124** may include a stop collar **125** to aid in positioning distal anchoring member **113** by controlling the depth of penetration of piercing tube **124** into the wall. A proximal portion of stop collar **125** is attached to the outside surface of a distal portion of piercing tube **124**. Stop collar **125** is cylindrical and has longitudinal slots spaced around a distal portion of the cylinder to form segments that are heat set or otherwise set such that they flare out away from the longitudinal axis of the cylinder when stop collar **125** is released from guiding sheath **122**. Stop collar **125** is seen contained within the lumen of guiding sheath **122** in **FIG. 1** and self-expanded into its preset flared configuration in **FIG. 2**. In **FIG. 3**, stop collar **125** has

- 15 -

been retracted back within guiding sheath **122** and is again radially compressed within the lumen of guiding sheath **122**.

[0053] Holding tube **126** and push cylinder **128** also comprise one or more biocompatible materials. Push cylinder **128** may be either a hollow or a solid elongated cylinder. Both holding tube **126** and push cylinder **128** must be flexible while still having sufficient rigidity to exert force on a heart chamber wall or an anchoring member, as described below.

[0054] An alternative embodiment of the system (not shown) resembles the embodiment described above, except that the tensioning device does not include locking members initially positioned between the proximal and distal anchoring members. In this embodiment, a locking member may be positioned proximal to the proximal anchoring member and be locked onto one or both of the tether and the proximal anchoring member to hold the tensioning device at a desired length. Alternatively, the tensioning device may be a preset length having a tether that is not adjustable.

[0055] Another aspect of the present invention is a method for treating mitral valve regurgitation by affecting a mitral valve annulus. **FIG. 6**, which shows a system for treating mitral valve regurgitation at an intermediate step of the method, is used throughout the following discussion as a reference for the structures of the heart.

[0056] A system for treating mitral valve regurgitation is delivered to a position adjacent to a first wall of a chamber of a heart. In the present embodiment, the system is system **100**, as described above, and the first wall is the septal wall between the right and left ventricles of the heart.

[0057] For delivery, system **100** is in the configuration shown in **FIG. 1**. Tensioning device **110** is slidably received within delivery catheter **120**. Arm segments **114** and **115** of proximal anchoring member **111** and distal anchoring member **113**, respectively, are in a folded, radially compressed configuration. Proximal anchoring member **111** is positioned within the lumen of holding tube **126**, while distal anchoring member **113** is positioned within the lumen of piercing tube **124**. Push cylinder **128** abuts the proximal end of

- 16 -

proximal anchoring member **111**. Holding tube **126** abuts the proximal end of distal anchoring member **113**.

[0058] Delivery catheter **120** carrying tensioning device **110** is passed through the venous system and into a patient's right ventricle. This may be accomplished as shown in **FIG. 6**, in which delivery catheter **120** has been inserted into either the jugular vein or the subclavian vein and passed through superior vena cava **602** into right atrium **604**, and then passed through tricuspid valve **606** into right ventricle **608**. Alternatively, the catheter may be inserted into the femoral vein and passed through the common iliac vein and the inferior vena cava into the right atrium, then through the tricuspid valve into the right ventricle. The procedure may be visualized using fluoroscopy, echocardiography, intravascular ultrasound, angioscopy, or other means of visualization.

[0059] The distal tip of delivery catheter **120** is positioned against the right ventricular surface of the septal wall. As described above, guiding sheath **122** of delivery catheter **120** includes a preformed or steerable distal tip that allows the delivery catheter to approach septal wall **610** in a desired orientation, for example at a 90-degree bend as shown in **FIG. 6**.

[0060] Delivery catheter **120** pierces the septal wall. This is accomplished by extending piercing tube **124** beyond the distal end of guiding sheath **122** until the tube pierces through the septal wall.

[0061] A distal anchoring member is then engaged with a second wall of the heart chamber. In the present embodiment, distal anchoring member **113** is engaged with the free wall of left ventricle **612** by being embedded within (i.e., between the surfaces of) the wall. To accomplish this, piercing tube **124** is advanced across the left ventricle and allowed to pierce into the free wall of left ventricle **612**. Stop collar **125**, which is attached to the outside surface of a distal portion of piercing tube **124**, remains constrained as seen in **FIG. 1** until it exits the septal wall, at which time it is free to self-expand into its preset configuration, as seen in **FIG. 2**. The expanded stop collar rests against the inside surface of the free wall of the left ventricle, controlling the

- 17 -

depth of penetration of piercing tube **124** into the wall and ensuring arm segments **115** are embedded between the two surfaces of the wall rather than extending through the wall. Guiding sheath **122** is not seen in **FIG. 2** as it remains in right ventricle **608**, supporting the delivery system while piercing tube **124** and its contents are advanced through the septal wall and across the left ventricle.

[0062] Distal anchoring member **113** is then pushed out of piercing tube **124** using holding tube **126**, at which time arm segments **115** are permitted to expand away from the body of distal anchoring member **113** and fix the distal anchoring member firmly within the wall. **FIG. 2** shows distal anchoring member **113** in its self-expanded configuration, having been released from delivery catheter **120**. Holding tube **126** is seen extended and resting against the proximal end of distal anchoring member **113**. **FIG. 6** also shows system **100** at this stage of deployment of tensioning member **110**.

[0063] Alternatively, distal anchoring member **113** may be delivered by extending piercing tube **124** to penetrate into or through the free wall of the left ventricle, and then retracting piercing tube **124** while holding distal anchoring member **113** stationary with holding tube **126**. Distal anchoring member **113** is thus released from the distal end of piercing tube **124** and permitted to self-expand within or beyond the wall. This alternative should be used where distal anchoring member **113** is to be positioned resting against the outside surface of the free wall.

[0064] Following deployment of the distal anchoring member, piercing tube **124** is withdrawn across the left ventricle, through the septal wall, and into guiding sheath **122**. Tether **112**, which links distal anchoring member **113** with proximal anchoring member **111**, is allowed to play out transverse the left ventricle as piercing tube **124** is withdrawn. Stop collar **125** returns to a radially compressed configuration as it passes through the septal wall and reenters the lumen of guiding sheath **122**.

[0065] Proximal anchoring member **111** is then deployed such that it engages with the septal wall. To accomplish this, proximal anchoring

- 17 -

- 18 -

member **111** is pushed out of holding tube **126** using push cylinder **128**, or holding tube **126** is withdrawn while proximal anchoring member **111** is maintained stationary with push cylinder **128**. Proximal anchoring member **111** is thus released from the distal end of piercing tube **124** and permitted to self-expand as seen in **FIG. 3**, either within or adjacent to septal wall **610**.

[0066] After proximal anchoring member **111** has been deployed, a locking member affixed to a tether linking the distal and proximal anchoring members is pulled from an initial position between the two anchoring members to a locked position proximal the proximal anchoring member. In the present embodiment, holding tube **126** is extended to rest against the expanded proximal anchoring member and act as a brace while tether **112** is being pulled in a proximal direction to adjust the tether to the desired length.

[0067] Shortening the length of the tether between the two anchoring members draws the walls of the left ventricle together and reduces both the radial tension on and the radial dimension of the mitral valve (seen in **FIG. 6** at **614**), thus improving coaptation of the valve leaflets and reducing regurgitation. At least one of the anchoring members, in the present embodiment the proximal anchoring member, flexes in response to a heartbeat when the anchoring members and tether are positioned across the heart chamber. This provides a shock absorbing effect that helps to protect the tensioning device from fatigue and reduces localized compressive pressure on tissue against which the flexing anchoring member rests.

[0068] The tensioning device may be placed in close proximity to the mitral valve, so that when the length of the tether between the proximal and distal anchoring members is adjusted, the outer cardiac wall is drawn toward the septal wall such that the anterior and posterior leaflets of the mitral valve are drawn together, thus reducing regurgitation. Alternatively, the tensioning device may be positioned across the left ventricle at an angle such that, for example, only one end of the device is anchored as close to the mitral valve annulus as possible. Two or more tensioning devices may also be placed across the left ventricle in parallel, crisscrossing, or in other patterns as believed by the treating clinician to best achieve the desired result of radially

- 18 -

- 19 -

compressing or relieving tension from the mitral valve. Alternatively, or in addition to ventricular placement, a tensioning device of the invention may be deployed across the left atrium, as approached from the right atrium, to radially compress or relieve tension from the mitral valve.

[0069] While the embodiments of the invention disclosed herein are presently considered to be preferred, various changes and modifications can be made without departing from the spirit and scope of the invention. The scope of the invention is indicated in the appended claims, and all changes and modifications that come within the meaning and range of equivalents are intended to be embraced therein.

- 19 -

- 20 -

What is claimed is:

1. A device for treating mitral valve regurgitation, comprising:
a tether;
a distal anchoring member positioned adjacent to a distal end of the tether; and
a proximal anchoring member positioned adjacent to a proximal end of the tether; wherein at least one of the anchoring members includes an elastic portion that flexes in response to a heart beat when the tensioning device is positioned across a chamber of a heart.
2. The device of claim 1 wherein the elastic portion comprises a material selected from a group consisting of a nickel-titanium alloy, a nickel-cobalt alloy, a cobalt alloy, a thermoset plastic, stainless steel, a biocompatible shape-memory material, a biocompatible superelastic material, and a combination thereof.
3. The device of claim 1 wherein the elastic portion comprises a plurality of flexible arm segments.
4. The device of claim 3 wherein the flexible arm segments are in a radially compressed, folded configuration while the anchoring member is within a lumen of a delivery catheter, and wherein the flexible arm segments self-expand when the anchoring member is released from the delivery catheter.
5. The device of claim 4 wherein the flexible arm segments of at least one of the anchoring members self-expand between the surfaces of a wall of a chamber of a heart.

- 21 -

6. The device of claim 1 wherein the tether comprises a material selected from a group consisting of stainless steel, titanium, a nickel-titanium alloy, a nickel-cobalt alloy, a cobalt alloy, tantalum, polypropylene, polyethylene, polyurethane, polytetrafluoroethylene (PTFE), polyester (Dacron®), nylon, a flexible and strong biocompatible material, and a combination thereof.

7. The device of claim 1 wherein at least a portion of the tether has a helical configuration.

8. The device of claim 1 wherein the tether includes a release loop adjacent to a proximal end of the tether.

9. The device of claim 1 further comprising:
at least one locking member affixed to the tether, wherein when the at least one locking member is pulled from an initial position between the proximal and distal anchors to a locked position proximal the proximal anchor, the length of the tether is adjusted to change the proximity of the anchoring members one to the other.

10. The device of claim 1 further comprising:
at least one sealing member.

11. The device of claim 1 wherein at least a portion of the tensioning device includes a therapeutic agent selected from a group consisting of an antithrombotic, an anticoagulant, an antibiotic, an anti-inflammatory, and a combination thereof.

12. A system for treating mitral valve regurgitation including the tensioning device of claim 1 and further comprising:
a delivery catheter, wherein the tensioning device is slidably received within a lumen of the delivery catheter.

- 21 -

- 22 -

13. The system of claim 12 wherein the delivery catheter comprises a guiding sheath, a piercing tube slidably received within a lumen of the guiding sheath, a holding tube slidably received within a lumen of the piercing tube, and a push cylinder slidably received within a lumen of the holding tube.

14. The system of claim 13 wherein the delivery catheter further comprises a stop collar attached to an outside surface of a distal portion of the piercing tube, and wherein a portion of the stop collar is self-expanding when the stop collar is positioned outside the lumen of the guiding sheath.

15. A system for treating mitral valve regurgitation, comprising:
a delivery catheter; and
a tensioning device received in the delivery catheter, the tensioning device including a tether, a distal anchoring member positioned adjacent to a distal end of the tether, a proximal anchoring member positioned adjacent to a proximal end of the tether, and at least one locking member affixed to the tether; wherein when the locking member is pulled from an initial position between the anchors to a locked position proximal the proximal anchoring member, the length of the tether is adjusted to change the proximity of the anchoring members one to the other.

16. The system of claim 15 wherein the tether includes a release loop adjacent to a proximal end of the tether.

17. The system of claim 15 wherein the locking member comprises a generally cylindrical member having a flexible tab flaring out from the cylindrical member.

18. The system of claim 15 wherein the locking member comprises a generally cylindrical member having an end shaped to form an angle with the longitudinal axis of the cylindrical member that is less than 90 degrees.

- 22 -

- 23 -

19. The system of claim 15 wherein at least one of the anchoring members includes an elastic portion that flexes in response to a heart beat when the tensioning device is positioned across a chamber of a heart.

20. The system of claim 19 wherein the elastic portion of the at least one anchoring member comprises a material selected from a group consisting of a nickel-titanium alloy, a nickel-cobalt alloy, a cobalt alloy, a thermoset plastic, stainless steel, a biocompatible shape-memory material, a biocompatible superelastic material, and a combination thereof.

21. The system of claim 19 wherein the elastic portion comprises a plurality of flexible arm segments.

22. The system of claim 21 wherein the flexible arm segments are in a radially compressed, folded configuration while the anchoring member is within a lumen of the delivery catheter and wherein the flexible arm segments self-expand when the anchoring member is released from the delivery catheter.

23. The system of claim 21 wherein the flexible arm segments of at least one of the anchoring members self-expand between the surfaces of a wall of a chamber of a heart.

24. The system of claim 15 wherein the tether comprises a material selected from a group consisting of stainless steel, titanium, a nickel-titanium alloy, a nickel-cobalt alloy, a cobalt alloy, tantalum, polypropylene, polyethylene, polyurethane, polytetrafluoroethylene (PTFE), polyester (Dacron®), nylon, a flexible and strong biocompatible material, and a combination thereof.

- 24 -

25. The system of claim 15 wherein at least a portion of the tensioning device includes a therapeutic agent selected from a group consisting of an antithrombotic, an anticoagulant, and a combination thereof.

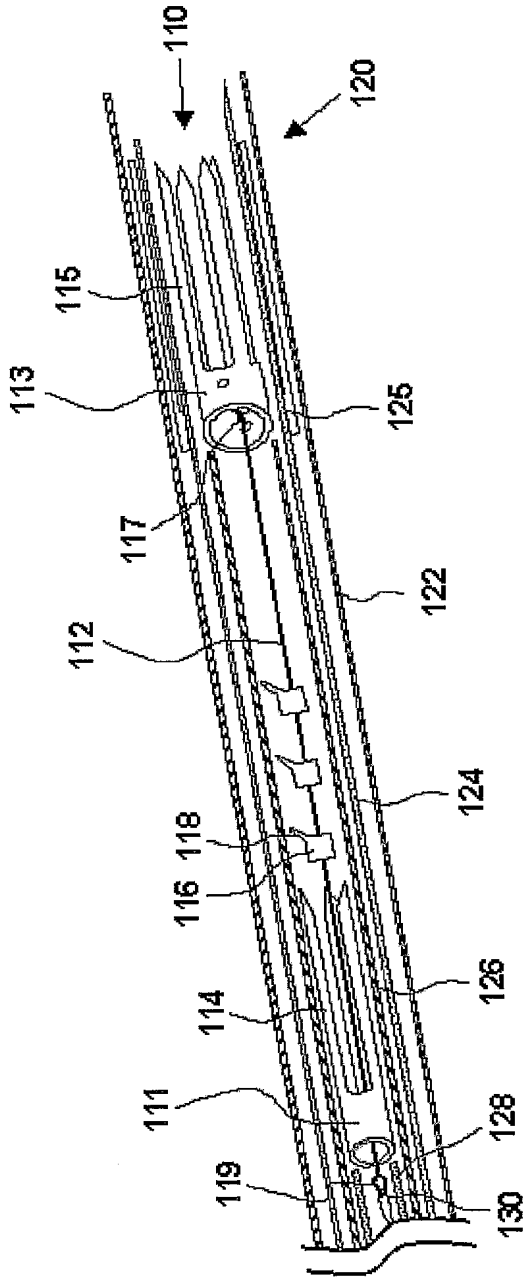
26. The system of claim 15 wherein the tensioning device includes at least one sealing member.

27. The system of claim 15 wherein the delivery catheter comprises a guiding sheath, a piercing tube slidably received within a lumen of the guiding sheath, a holding tube slidably received within a lumen of the piercing tube, and a push cylinder slidably received within a lumen of the holding tube.

28. The system of claim 27 wherein the delivery catheter further comprises a stop collar attached to an outside surface of a distal portion of the piercing tube, and wherein a portion of the stop collar is self-expanding when the stop collar is positioned outside the lumen of the guiding sheath.

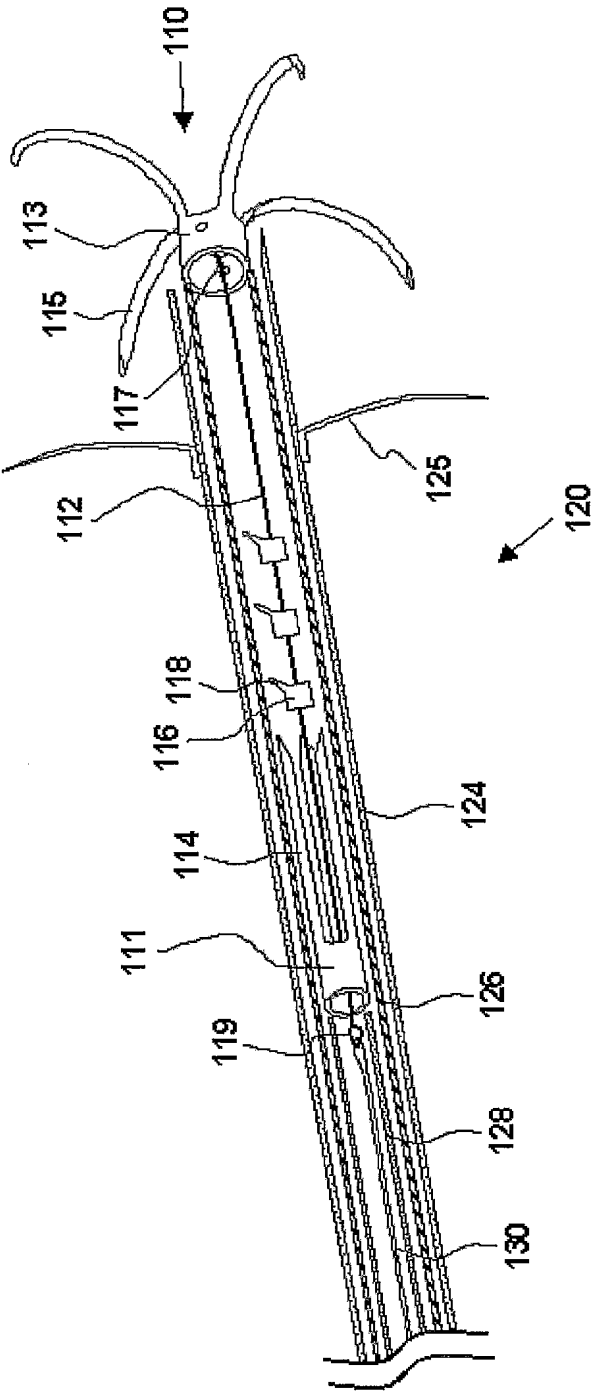
100

FIG. 1



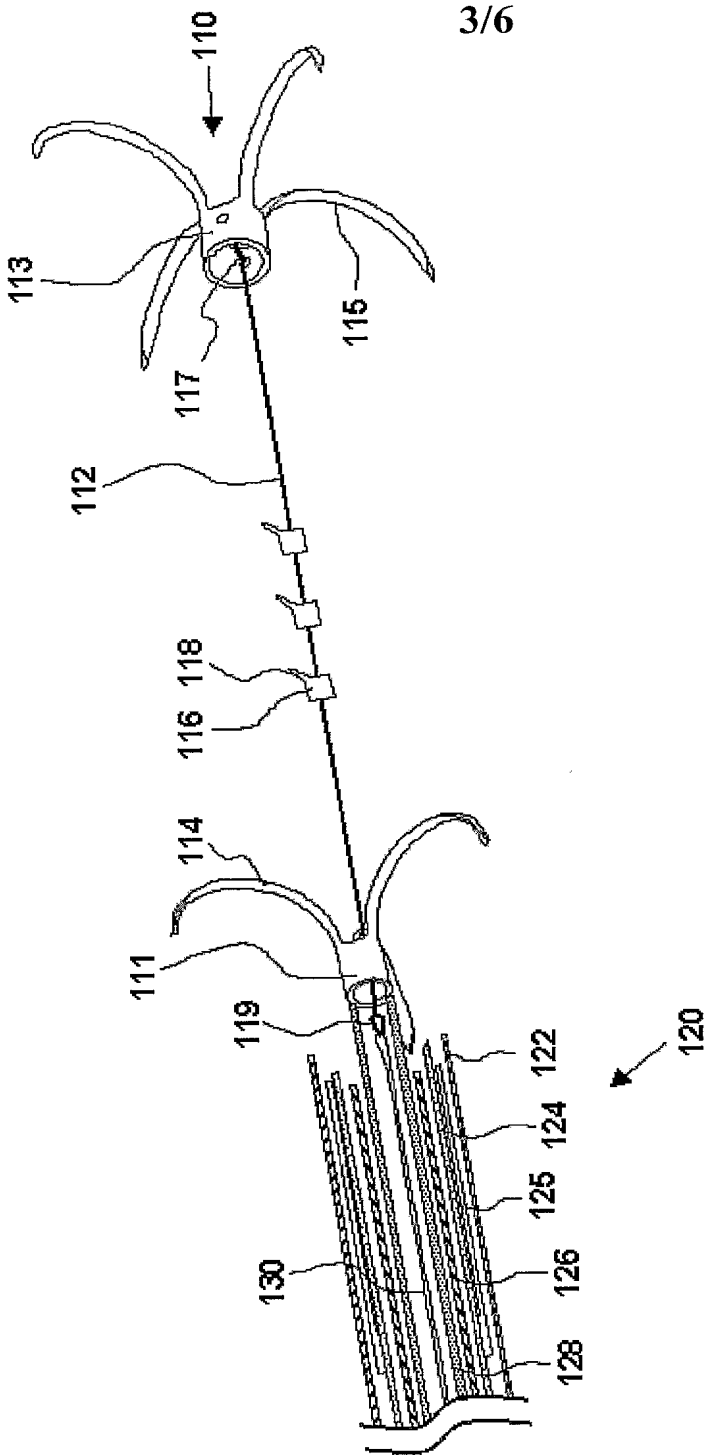
100

FIG. 2



100

FIG. 3



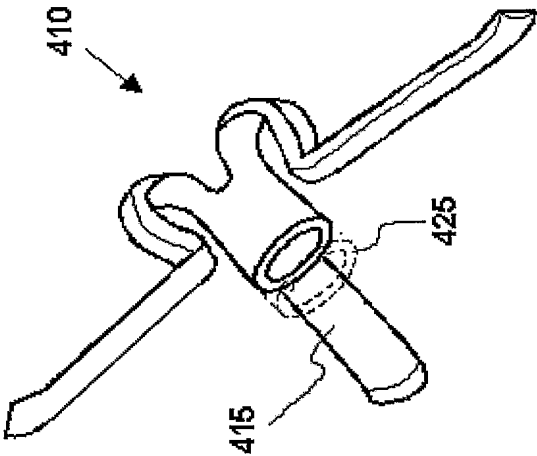


FIG. 4B

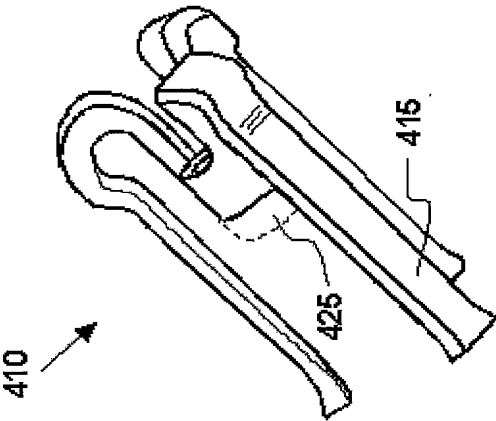
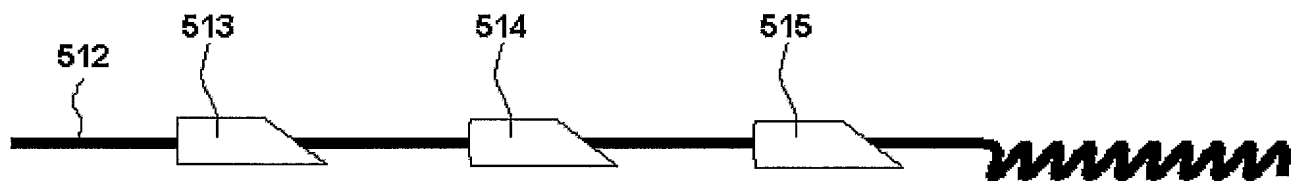
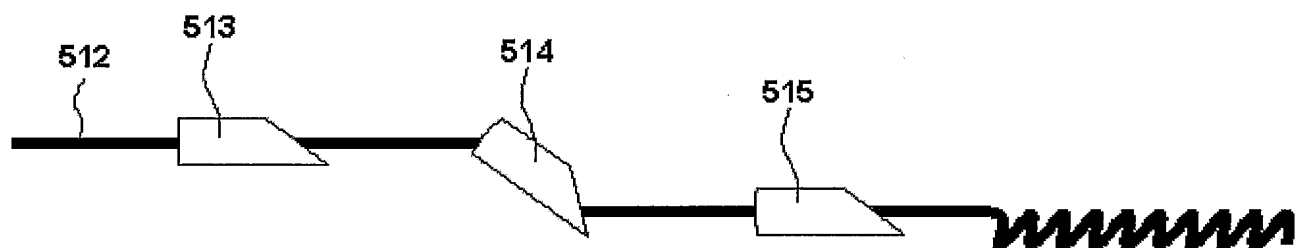


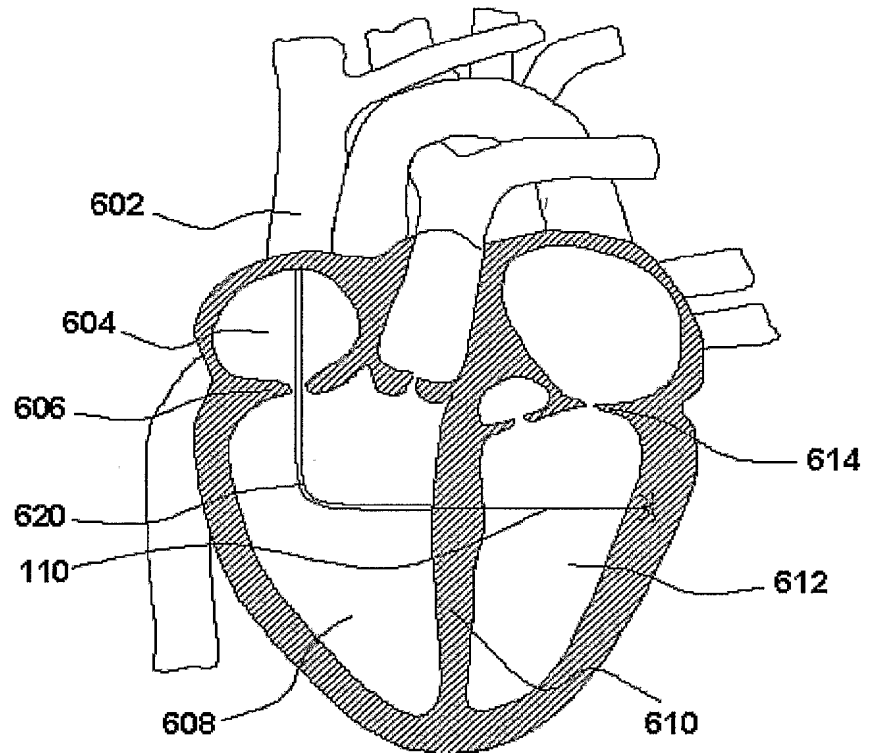
FIG. 4A

5/6

FIG. 5A**FIG. 5B**

6/6

FIG. 6



INTERNATIONAL SEARCH REPORT

International Application No
PCT/US2004/019745

A. CLASSIFICATION OF SUBJECT MATTER

IPC 7 A61F2/24

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 7 A61F A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 02/30335 A (SCHROEDER RICHARD F ; SCHWEICH CYRIL J JR (US); KEITH PETER T (US); SI) 18 April 2002 (2002-04-18) page 13, line 1 - page 36, line 20	1-8, 10-14
A	-----	9, 15-28
A	WO 00/60995 A (EVALVE INC) 19 October 2000 (2000-10-19) figures 39a,b figures 44a-46a page 38, line 19 - page 40, line 33	1-28
A,P	US 2003/158570 A1 (FERRAZZI PAOLO) 21 August 2003 (2003-08-21) paragraph '0068! - paragraph '0088!	1-28
A	US 2002/188170 A1 (SANTAMORE WILLIAM P ET AL) 12 December 2002 (2002-12-12) paragraph '0107! - paragraph '0251!	1-28

☐

Further documents are listed in the continuation of box C.

☒

Patent family members are listed in annex.

* Special categories of cited documents:

- *A* document defining the general state of the art which is not considered to be of particular relevance
- *E* earlier document but published on or after the international filing date
- *I* document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
- *O* document referring to an oral disclosure, use, exhibition or other means
- *P* document published prior to the international filing date but later than the priority date claimed

- *T* later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
- *X* document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
- *Y* document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.
- *G* document member of the same patent family

Date of the actual completion of the international search

12 November 2004

Date of mailing of the international search report

19/11/2004

Name and mailing address of the ISA

European Patent Office, P.B. 5818 Patentlaan 2
NL - 2280 HV Rijswijk
Tel. (+31-70) 340-2040, Tx. 31 651 epo nl,
Fax: (+31-70) 340-3016

Authorized officer

Mary, C

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No

PCT/US2004/019745

Patent document cited in search report		Publication date	Patent family member(s)	Publication date
WO 0230335	A	18-04-2002	US 6616684 B1	09-09-2003
			AU 9492101 A	22-04-2002
			EP 1322259 A2	02-07-2003
			WO 0230335 A2	18-04-2002
			US 2003181928 A1	25-09-2003
WO 0060995	A	19-10-2000	AU 770243 B2	19-02-2004
			AU 4211800 A	14-11-2000
			CA 2369641 A1	19-10-2000
			EP 1176913 A2	06-02-2002
			JP 2002540878 T	03-12-2002
			WO 0060995 A2	19-10-2000
			US 2004092962 A1	13-05-2004
			US 2004049207 A1	11-03-2004
			US 2004087975 A1	06-05-2004
			US 2004044350 A1	04-03-2004
			US 6629534 B1	07-10-2003
			US 2004003819 A1	08-01-2004
			US 2004030382 A1	12-02-2004
			US 2004039442 A1	26-02-2004
			US 2002013571 A1	31-01-2002
US 2003158570	A1	21-08-2003	IT PC20000013 A1	12-07-2000
			AU 4682601 A	30-10-2001
			CA 2405382 A1	25-10-2001
			CN 1422139 T	04-06-2003
			CZ 20023737 A3	12-02-2003
			EA 4187 B1	26-02-2004
			EP 1272123 A1	08-01-2003
			WO 0178625 A1	25-10-2001
			JP 2003530199 T	14-10-2003
			NZ 521815 A	25-06-2004
			PL 357685 A1	26-07-2004
			SK 16142002 A3	01-04-2003
			ZA 200209008 A	09-07-2003
US 2002188170	A1	12-12-2002	WO 03090716 A1	06-11-2003
			US 2003078671 A1	24-04-2003
			CA 2445281 A1	07-11-2002
			EP 1395214 A1	10-03-2004
			WO 02087481 A1	07-11-2002